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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,745	11/18/2003	Osman Rathore	VTN 5001CIP	4390
27777	7590	06/20/2007		
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			EXAMINER PERREIRA, MELISSA JEAN	
			ART UNIT	PAPER NUMBER
			1618	
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			06/20/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/715,745	<b>Applicant(s)</b> RATHORE ET AL.	
	<b>Examiner</b> Melissa Perreira	<b>Art Unit</b> 1618	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 November 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 November 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____  |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date  
:6/8/04,2/7/05,9/16/05,10/13/05,12/5/05.

## DETAILED ACTION

### *Priority*

1. The instant claims 1,9,23,25 and 28 are afforded the priority date of 12/21/00 of the provisional application 60/257,030 and the instant claims 18,21,22,24,26 and 29 are afforded the priority date 11/22/02 as the limitations of these claims are found in the provisional application 60/428,620. The instant claims 2-8,10-17,19,20,27 and 30-35 are afforded the priority date 11/18/03 as the limitation of these claims are not found in the provisional applications specified.

2. If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 119 (e), a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the **first sentence(s) of the specification following the title or in an application data sheet**. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. **The provisional application 60/257,030 to which parent application 10/028,400 is not designated in the specification.**

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the

application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge

under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

### ***Oath/Declaration***

The Oath and Declaration does not designate any of the priority documents.

### ***Drawings***

3. The drawings are objected to because the figures 3,4 and 5 recite “ppm Ag in l ns” on the y axis. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the

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examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

4. The disclosure is objected to because of the following informalities: The specification does not designate the provisional application 60/257,030 to which parent application 10/028,400 claims priority to. Appropriate correction is required.
5. The disclosure is objected to because of the following informalities: page 2 of the specification describes figure 5 and the amount of silver released from a contact lens containing three different kinds of silver compounds but in the drawings figure 5 shows four compounds in the legend. Appropriate correction is required.

### ***Claim Objections***

6. Claim 35 is objected to because of the following informalities: the claim recites "05 log" instead of .05 log. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:  

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
8. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear as to what constitutes, "substantially free from

visible haze". There is no guidance provided in the specification as to degree of haziness that would be appropriate for the invention of the instant claims.

9. Claims 21 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear as to what applicant considers the silver releasing compound of the instant claims. There is no mention of a silver releasing compound in claim 1 to which the instant claims depend.

10. Claims 21 and 22 recite the limitation "silver releasing compound". There is insufficient antecedent basis for this limitation in the claims. There is no mention of a silver releasing compound in claim 1 to which the instant claims depend.

11. Claims 26 and 29 recite the limitation "said reaction mixture". There is insufficient antecedent basis for this limitation in the claims. There is no mention of a reaction mixture in claim 1 to which the instant claims depend.

### ***Claim Rejections - 35 USC § 102***

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.



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13. Claims 1,8-12,16,19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Shimai et al. (JP07-270726A).

14. Shimai et al. (JP07-270726A) teaches of a comfortable contact lens containing silver ions and a polymer (i.e. polymethacrylate) (claims 1,2; p3, [0006-0007]; p4, [0010]) which provides for less bacterial breeding (p4, [0008]; p8, [0034]). The injected amount of silver ions is  $1 \times 10^{15}$  ions/cm<sup>2</sup> (table 1). The contact lenses of the disclosure encompass those of the instant claims, should have the same properties and be capable of the same functions, such as providing for a reduction in microbial activity of at least 50, 70 or 90%, not cause argyria and be free from visible haze.

It is respectfully pointed out that instant claims 1,11,19 and 20 are product-by-process limitations. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

15. Claims 1,8-12,16,19,23 and 25-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Christ (US 5,843,186).

16. Christ (US 5,843,186) teaches of transparent intraocular lenses that comprises a polymer, such as silicone (column 1, line 47; column 7, lines 11 and 16; column 8, lines

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21-23 and 50-53), a hydrophilic polymer and an antimicrobial agent, such as silver (column 10, lines 53-56). The hydrophilic material may also act as a coating. The antimicrobial agent, silver, will be liberated from the polymer surface and into the surrounding medium (column 6, lines 7-13; column 7, lines 47-50). The foremost advantage of the intraocular lenses of the disclosure is that bactericidal potency is maximized because the metal is guaranteed to go into solution as ions, thus producing a minimum ten-fold reduction in bacterial colonization rate (column 11, lines 34-37). The contact lenses of the disclosure encompass those of the instant claims, should have the same properties and be capable of the same functions, such as providing for a reduction in microbial activity of at least 50, 70 or 90%, not cause argyria and be free from visible haze.

It is respectfully pointed out that instant claims 1, 11, 19, 20, 25, 28 and 30 are product-by-process limitations. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

17. Claims 1 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Barry et al. (EP1050314A1) and claims 8-12,16,19,20,23 and 25-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Barry et al. (EP1050314A1).

18. Barry et al. (EP1050314A1) teaches of an antimicrobial and optically clear ocular lens comprising a polymer, such as silicone (column 9, [0043]) and zeolite, containing antimicrobial silver (column 3, [0013]; column 7, [0034-35]), where the lens is resistant to microbial growth in the body or on the surface of the lens (column 3, [0011]; column 5, [0023]). The antimicrobial agent, such as silver (abstract; column 1 [0005]) is incorporated into the lens (abstract; column 4 [0021]; column 5, [0024]) or may be used as a coating. Silver is particularly safe and nontoxic for the use in contact lenses due to the fact that they are not substantially absorbed into the body and not cause discoloration of the lens over time (abstract; column 9, [0042]). The ion-exchanged silver ions are present in a concentration of about 0.01 to 5 wt% in the zeolite which is included in the polymeric matrix or is in an effective amount to achieve antimicrobial properties (column 3, [00130]; column 4, [0020]). The ion release rate of the silver in the lenses is less than about 100 parts per billion per day (column 8, [0037]). The coating material includes polymers, i.e. hydrophilic polymers, hydrogels, etc. (column 10, [0047]). The ocular lenses of the disclosure encompass those of the instant claims, should have the same properties and be capable of the same functions, such as providing for a reduction in microbial activity of at least 50, 70 or 90%, not cause argyria and be free from visible haze.

It is respectfully pointed out that instant claims 1,11,19,20,25,28 and 30 are product-by-process limitations. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

***Claim Rejections - 35 USC § 103***

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. Claims 1-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Christ (US 5,843,186) in view of Tanaka et al. (US 4,139,513) in further view of Dziabo et al. (US 5,340,583) or Maiden et al. (US 6,367,929B1) or Nissen et al. (*Ophthalmologie* 2000, Sept., 97, 640-643; translation).

21. Christ (US 5,843,186) discloses a transparent intraocular lens that comprises a polymer, such as silicone (column 1, line 47; column 7, lines 11 and 16; column 8, lines 21-23 and 50-53), a hydrophilic polymer and an antimicrobial agent, such as silver (column 10, lines 53-56). The hydrophilic material may also act as a coating. The

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antimicrobial agent, silver, will be liberated from the polymer surface and into the surrounding medium (column 6, lines 7-13; column 7, lines 47-50). The foremost advantage of the intraocular lenses of the disclosure is that bactericidal potency is maximized because the metal is guaranteed to go into solution as ions, thus producing a minimum ten-fold reduction in bacterial colonization rate (column 11, lines 34-37). Christ (US 5,843,186) does not disclose a continuous wear contact lens or that the polymer contains a ligand for releasably binding the silver.

22. Tanaka et al. (US 4,139,513) discloses a copolymer suitable for use in soft contact lenses which can be continuously worn for long term comprising at least one siloxy monomer and a hydrophilic monomer (column 1, lines 64-65; column 2, lines 13 and 44). Silicone rubber contact lenses are unfavorable for use as they have different properties from that of the cornea, thus giving a foreign body sensation (burning), are easily contaminated and are weaker in quality, etc (column 1, lines 24-47). The siloxane bond raises the oxygen permeability but provides a strong water repellent property, thus causing a burning sensation whereas the inclusion of the hydrophilic monomer into the polymer matrix reduces the burning sensation but increases the opacity (column 3, lines 11-33). However, the inclusion of the hydrophilic monomer in the precise amount designated in the disclosure provides for the following advantages, such as the contact lenses of the disclosure can be worn comfortably for about 21 days (column 6, line 13) without giving a foreign body sensation or pain, are colorless/transparent and have excellent oxygen permeability (column 1, lines 14-16 and 66-68; column 3, lines 34-40). No change was observed during a continuous wear

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experiment which was conducted for 21 days. The experiment was conducted for 21 days as it is known that the cycle of metabolism of cornea is about 18 days (column 6, lines 26-27).

23. In regards to claim 15, Dziabo et al. (US 5,340,583) discloses ophthalmic devices, such as contact lenses or contact lens cases where the antimicrobial component, such as silver is covalently bound to the polymeric materials (column 1, lines 8-12; claims 1,5,9 and 10). The reactive polymeric material, such as polysiloxanes contains a group/ligand that reacts with the antimicrobial component (column 4, lines 26 and 63+; column 5 lines 1-9).

24. At the time of the invention it would have been obvious to one ordinarily skilled in the art utilize a polysiloxane polymeric material containing a silver binding ligand to control the release of the silver ions into solution and thus avoid any allergic reactions. It would have been obvious to utilize material that can afford continuous wear as it is inconvenient and costly to have to change ones contact lenses frequently. One would have a reasonable expectation of success for using the contact lens materials of Tanaka et al. in combination with the silver binding ligand of Dziabo et al. to produce an anti-allergy, anti-microbial, comfortable and cost-effective contact lens. The silver releasing compound of the disclosure encompasses that of the instant claims and therefore should have the same properties, such as molar solubility.

25. Christ (US 5,843,186) also does not disclose the silicone hydrogel being one listed in the instant claims 24 or the reduction in microbial colonization of the instant claims.

26. In regards to claim 24, Maiden et al. (US 6,367,929B1) discloses hydrophobic silicone hydrogels suitable for ophthalmic lenses with high oxygen permeability and wettability. The hydrogels comprise a hydrophilic monomer entrapped in a silicone hydrogel monomer matrix (column 2, lines 6-14). The surface of the contact lenses may be coated with a hydrophilic coating to improve the physiological compatibility of the lenses with the surface of the eye (column 5, lines 41-47). The silicone hydrogels of the disclosure have O<sub>2</sub> Dk values for oxygen permeability of between 40 and 300 barrer and are similar to Balafilcone A contact lenses which give a measurement of approximately 79 barrer (column 8, lines 62+; column 9, lines 3-6).

27. In regards to claims 31-35, Nissen et al. (*Ophthalmologie* **2000**, Sept., 97, 640-643; translation) discloses contact lenses provided with a silver layer to provide for antimicrobial action against microbes. The attenuation of the germ load on the silver coated contact lenses was 6 logs in step compared to uncoated lenses for *Pseudomonas aeruginosa* and 1.5 log steps in the case of *Staphylococcus aureus* (p5, results). The silver is present in traces on the lenses and in the concentration range of 50-500 µg/L. When wearing such lenses, argyria which occurs at significantly higher concentrations is not expected (p7, paragraph 3).

28. At the time of the invention it would have been obvious to one ordinarily skilled in the art to utilize the contact materials of Maiden et al. or Balafilcone A for the preparation

of contact lens material as they are equivalent. These materials have increased oxygen permeability and wettability and are thus more comfortable for the wearer. One would have a reasonable expectation for success for reducing the microbial colonization by at least 6 logs or 1.5 log steps by utilizing silver as the antimicrobial agent as disclosed by Nissen et al.

It is respectfully pointed out that instant claims 1,11,19,20,25,28 and 30 are product-by-process limitations. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

### ***Double Patenting***

29. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).



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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

30. Claims 1,5-11,16,19,20,25 and 28 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 27-30,33-39 and 53 of copending Application No. 10/183,883. Although the conflicting claims are not identical, they are not patentably distinct from each other because the ophthalmic device of the instant claims encompasses the antimicrobial lens of 10/183,883. The device of the instant claims comprises a contact lens containing a silver antimicrobial agent and anticipates the antimicrobial lens/contact lens of 10/183,883. The lenses of both disclosures contain the antimicrobial agents in a concentration from 0.1 to about 200,000ppm and should have the same properties and be capable of the same functions, such as providing for a reduction in microbial activity of at least 50, 70 or 90% and not causing argyria.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

31. Claims 1,5-11,16,19,20,26 and 29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4,18-20,23,26 and 29-31 of copending Application No. 11/291,462. Although the

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conflicting claims are not identical, they are not patentably distinct from each other because the ophthalmic device of the instant claims encompasses the antimicrobial lens of 10/183,883. The device of the instant claims comprises a contact lens containing a silver antimicrobial agent and anticipates the antimicrobial lens/contact lens of 11/291,462. The lenses of both disclosures contain the antimicrobial agents, such as silver in a concentration from 0.02 to about 1.0 wt % and should have the same properties and be capable of the same functions, such as providing for a reduction in microbial activity of at least 50, 70 or 90% and not causing argyria.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

No claims are allowed at this time.

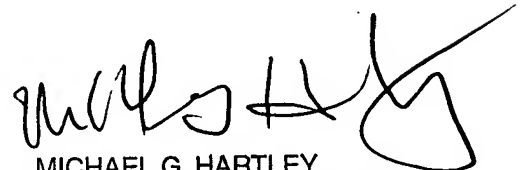
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Perreira whose telephone number is 571-272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MP  
May 30, 2007

A handwritten signature in black ink, appearing to read 'Michael G. Hartley', with a large, stylized flourish at the end.

MICHAEL G. HARTLEY  
SUPERVISORY PATENT EXAMINER